

5

We claim:

1. A manufacturing process for the conversion and incorporation of a salt or free
10 base of an active pharmaceutical ingredient into a therapeutic liquid or semi-solid
dosage form, the process comprising the steps of:

(a) dissolving the salt or free base of the active pharmaceutical ingredient
in a pharmaceutically acceptable liquid in the presence of a dispersing
agent and tannic acid under stirring, to form a dispersion wherein the
15 tannic acid component is of either a natural or synthetic source;
(b) combining the tannate salt complex of the active pharmaceutical
ingredient without isolation or purification with pharmaceutically
acceptable excipients to generate a therapeutic dosage form.

2. The process according to claim 1 wherein the dispersing agent provided in
step (b) is selected from the group consisting of magnesium aluminum silicate,
xanthan gum and cellulose compounds.

3. The process according to claim 1 wherein the pharmaceutically acceptable liquid in step (a) is selected from the groups consisting of purified water, isopropyl alcohol, ethanol, glycerin, propylene glycol, mineral oil and mixtures thereof.

4. The process according to claim 1 wherein without isolation or purification of the tannate salt or complex of the active pharmaceutical ingredient, the additional steps are:

(c) separately adding one or more of the following; thickening, suspending, coloring, sweetening and flavoring agents to water under stirring, to form a dispersion;

5 (d) adding the tannate salt suspension from step (a) to the dispersion in step (c), under stirring to form a mixture containing the tannate salt complex of the active pharmaceutical ingredient;

(e) separately adding one or more of the following; preservative, pH adjusting and anti-caking agents to a pharmaceutically acceptable liquid under stirring to form a dispersion; and

10 (f) adding the dispersion from step (e) to the mixture from step (d) under stirring, to generate a suspension dosage form, at a pH range of 3.5-8.0.

5. A manufacturing process for the conversion and incorporation of a salt or free base of an active pharmaceutical ingredient selected from the group consisting of

an antihistamine, a decongestant, an antitussive and an anticholinergic for incorporation into a therapeutic liquid or semi-solid dosage form, the process comprising the steps of:

- 5 (a) dissolving the salt or free base of the active pharmaceutical ingredient in a pharmaceutically acceptable liquid in the presence of a dispersing agent and tannic acid under stirring, to form a dispersion wherein the tannic acid component is of either a natural or synthetic source;
- (b) combining the tannate salt complex of the active pharmaceutical ingredient without isolation or purification with pharmaceutically
- 10 acceptable excipients to generate a therapeutic dosage form.

6. The process according to claim 5 wherein the antihistamine active pharmaceutical ingredient is selected from the group consisting of: carbinoxamine, chlorpheniramine, pyrilamine, pheniramine, phenindamine, diphenhydramine, bromodiphenhydramine, brompheniramine, loratadine, desloratadine, fexofenadine, cetirizine, hydroxyzine, promethazine, acrivastine, triprolidine, meclizine, dimenhydrinate, triplennamine, doxylamine, diphenylpyrilamine, trimeprazine; and chlorcyclizine.

7. The process according to claim 5 wherein the antitussive active pharmaceutical ingredient is selected from the group consisting of: carbetapentane, dextromethorphan, diphenhydramine, codeine, hydrocodone, oxycodone, and morphine.

8. The process according to claim 5 wherein the decongestant active pharmaceutical ingredient is selected from the group consisting of: phenylephrine, pseudoephedrine, ephedrine, diphenhydramine, cyproheptadine, phenyltoloxamine, and clemastine.
9. The process according to claim 5 wherein the anticholinergic active pharmaceutical ingredient is methscopolamine.
10. The process according to claim 5 wherein the antihistamine and decongestants active ingredients are provided as the bitartrate, maleate, citrate, chloride, bromide, acetate or sulfate salt.
11. The process according to claim 5 wherein the tannic acid provided in step (a) is natural or synthetic.
12. The process according to claim 5 wherein a mixture of antihistamine tannate and decongestant tannate salts are formed in step (b).
13. The process according to claim 12 wherein the antihistamine tannate and decongestant tannate salts in step (b) comprise carbetapentane tannate, phenylephrine tannate and pyrilamine tannate.

14. The process according to claim 12 wherein the antihistamine tannate and decongestant tannate salts in step (b) comprise pyrilamine tannate and phenylephrine tannate.

15. The process according to claim 12 wherein the antihistamine tannate and decongestant tannate salts in step (b) comprise pseudoephedrine tannate and chlorpheniramine tannate.

16. A manufacturing process for the conversion and incorporation of a salt or free base of an active pharmaceutical ingredient into a therapeutic liquid or semi-solid dosage form, the process comprising the steps of:

- 5 dissolving the salt or free base of the pharmaceutical ingredient and tannic acid in a pharmaceutically acceptable liquid to form a dispersion; and
 adding at least one pharmaceutically acceptable excipient to said dispersion to generate a therapeutic dosage form.

17. The process of claim 16, further including completing the dissolving and adding steps in a single vessel.

18. The process of claim 17, further including generating said therapeutic dosage form without isolating or purifying a resulting tannate salt complex of the active pharmaceutical ingredient.

19. The process of claim 16, further including generating said therapeutic dosage form without isolating or purifying a resulting tannate salt complex of the active pharmaceutical ingredient.